K112162

MIS Implants Technologies Ltd.

AUG 8 2012

510(k) Summary:

Conical Connection Dental Implants

Company Name: MIS Implants Technologies Ltd.
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Establishment Registration Number: 3004203816

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Date prepared: July 13, 2011

Trade Name: Conical Connection Implants

Classification name: Implants, Endosseous, Root Form

Common/usual name: Dental Implant

Product Code: DZE; NHA

Regulation No.: 872.3640

Class: II

Panel identification: Dental Devices Panel

Predicate Device:

MIS Implants Technologies Ltd. dental implants Seven, Biocom and Lance, cleared under 510(k) K040807.

Description of the device:

The conical connection dental implants are self tapping, root-form, two piece screw type dental implants, indicated for use in surgical and restorative applications for placement in the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function.

The conical connection dental implants are provided in 3.75, 4.2 and 5.0 mm diameters and with the following lengths:

- 3.75mm diameter: 8mm, 10mm, 11.5mm, 13mm and 16mm
- 4.2mm diameter: 8mm, 10mm, 11.5mm, 13mm and 16mm
- 5.0mm diameter: 8mm, 10mm, 11.5mm, 13mm and 16mm

The implants surface is sand blasted and acid etched .

The conical connection dental implants are two piece devices whereas the implant is to be used in combination with cover screws, healing caps, abutments and superstructures.

The conical connection dental implants are made of Ti6AL4V ELI complying with standard ASTM F 136-08- Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant.

The conical connection dental implants were modified to integrate a new type of connection, internal conical connection of 6 degrees with an anti-rotation index of six positions, ensuring a more definite seal and a more stable connection.

Indications for Use:

MIS Conical Connection Implants are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.

When a one stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate.

Substantial Equivalence:

- Technological characteristics – comparative table:

	Conical Connection Implants from MIS Implants Technologies Ltd.	**Seven, Biocom and Lance Implants from MIS Implants Technologies Ltd.**
510(k) number	K112162	K040807
Product Code	DZE/NHA	DZE/NHA
Indications For Use	MIS Conical Connection Implants are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function. When a one stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate.	MIS dental implants are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.
Supplied Sterile	Yes	Yes
Re-use	No	No
Material of Construction	Titanium Alloy – Ti6Al4V ELI	Titanium Alloy – Ti6Al4V ELI
Surface treatment	Sand blasted, acid etched and anodized	Sand blasted and acid etched
Shape	Screw type	Screw type
Thread Diameter	3.75, 4.2 and 5.0 mm	3.75, 4.2 and 5.0 mm
Length	8, 10, 11.5, 13 and 16 mm	8, 10, 11.5, 13 and 16 mm
Internal Connection	Conical	Hexagonal
Abutments	Straight and up to 25° angled	Straight and up to 25° angled

	Conical Connection Implants from MIS Implants Technologies Ltd.	Seven, Biocom and Lance Implants from MIS Implants Technologies Ltd.
Material of Construction of Abutments	Titanium Alloy – Ti6Al4V ELI	Titanium Alloy – Ti6Al4V ELI
Surface treatment of Abutments	Anodized	None
Abutments Connection	Conical	Hexagonal

- Non – clinical tests:

Fatigue test was performed on MIS conical connection implants and its results were found comparable to those of their predicate devices.

- Clinical tests:

A preliminary clinical evaluation, based on case studies with six months follow up has been performed, showing good stability of the conical connection implant.

Conclusion:

The evaluation of the conical connection dental implants does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Iman Khorshid
Vice President of Quality Assurance & Regulatory Affairs
MIS Implants Technologies Limited
P.O. Box 7, Bar Lev Industrial Park
20156, Israel

AUG 8 2012

Re: K112162
Trade/Device Name: MIS Conical Connection Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: July 26, 2012
Received: July 27, 2012

Dear Ms. Khorshid:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MIS Implants Technologies Ltd.

INDICATIONS FOR USE

510(k) Number (if known): K112162

Device Name: Conical Connection Implants

Indications for Use: MIS Conical Connection Implants are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.
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Prescription Use ___X___ OR Over the Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112162